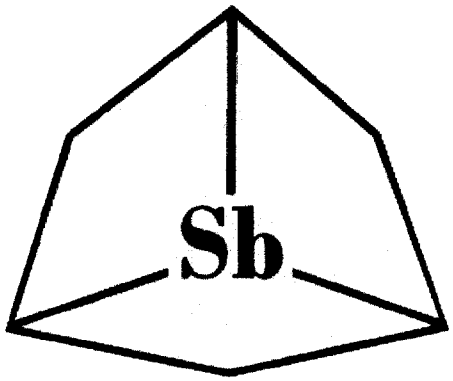
8EHQ-0304-15523

MR 273673



International
ANTIMONY OXIDE
Industry Association

VIA CERTIFIED MAIL

March 2, 2004

CONTAINS NO CBI

Document Processing Center
Mail Code 7407M
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Attention: TSCA Section 8(e) Coordinator

RE: TSCA Section 8(e) Notification on Antimony Trioxide
(CAS No.: 1309-64-4)

Dear Sir or Madam:

The mission of the International Antimony Oxide Industry Association (IAOIA)[1] is to serve the common interests of antimony producers, users, and other stake holders world-wide concerning the environmental health and safety regulatory affairs concerning antimony substances and their uses. The activities of the IAOIA include the conducting of studies, dissemination of information pertaining to the safety and benefits of antimony substances and the development of scientific information for submission to governmental agencies. As such, the IAOIA submits this letter of substantial risk notification in accordance with Section 8(e) of the Toxic Substances Control Act, 15 USC 2607(e), and the Environmental Protection Agency's "Notification of Substantial Risk; Policy Clarification and Reporting Guidance", 68

[1] The International Antimony Oxide Industry Association consists of the following producers of antimony trioxide: Campine NV, Great Lakes Chemical Corp., Laurel Industries, Inc. (OxyChem), Penox SA, Produit Chimiques de Lucette, Sica, Nihon Seiko Co., LTD., Nissan Chemical Industries, LTD., Yamanaka and Co., Ltd.., Sumitomo Metal Mining Co., LTD., and Tohko Industrial Corporation.

FR33129, 40 seq., June 3, 2003. The notification is in regards to a report sponsored by IAOIA (addresses and contact information in Appendix A) entitled, "An inhalation developmental toxicity study in rats with antimony trioxide". This notification is submitted by and on behalf of the U.S. members of the IAOIA, specifically Great Lakes Chemical Corp. and Laurel Industries, Inc.

The study, "An inhalation developmental toxicity study in rats with antimony trioxide", was performed under contract with the IAOIA by MPI Research Inc., 54943 North Main Street, Mattawan, MI 49071-9399. The test material, Antimony trioxide (CAS No.: 1309-64-4) was administered via nose-only inhalation to groups of 26 female rats at target concentrations of 0, 1.5, 3.0, or 6.0 mg/M^3 for 6 hours per day from Days 0 through 19 of gestation. A concurrent control group of identical design received clean, filtered air on a comparable regimen. All animals survived the study and no effect of treatment was evident from maternal clinical examinations, gestation body weight, or food consumption. Likewise, no effect of treatment was evident from maternal macroscopic findings, Day 20 gestation uterine implantation data, fetal sex ratios, fetal body weights, fetal crown rump-distance data or fetal examinations (external, visceral, or skeletal). While the study did not induce fetal toxicity at any of the concentrations employed, maternal effects were observed at every concentration level, 2.6, 4.4, or 6.3 mg/m^3 (actual delivered concentrations). This was manifested as increases in lung weights, which were 24%, 31%, and 39% greater than controls for the 2.6, 4.4, and 6.3 mg/m^3 groups, respectively. Further histopathological analysis, which was conducted specifically to delineate the reason for these increases revealed diffuse accumulation of pigmented alveolar macrophages which likely reflected phagocytosis and accumulation of the test article particulate matter. It was concluded that these findings are typical with exposures to particulate matter, especially when the route of exposure is nose-only.

These types of findings were observed in 13-week and 1-year inhalation studies in Fischer 344 rats (Newton et al., 1994) sponsored by the Antimony Oxide Industry Association (AOIA). Rats in the 13-week study receiving 4.92 and 23.46 mg/m^3 had significantly increased absolute and relative lung weights. While a similar increase in lung weights was not observed in the 1-year inhalation study (0.05, 0.5, and 5.0 mg/m^3), a similar histopathological profile was observed coinciding with large tissue burdens of the particulate. In the 13-week and 1-year studies, a different strain of rat was used and the route of exposure was whole-body inhalation. Also, the particle size of the test material was 3.05 ± 0.21 and 3.76 ± 0.84 microns in the subchronic and chronic studies, respectively. In the current developmental study, particle size ranged from 1.59 to 1.82 microns. While the findings of the recently conducted developmental study do not provide evidence of a new or unexpected effect, changes in lung weights and histopathological findings were observed with a shorter duration of exposure.

The Lowest Observable Adverse Effect Level (LOAEL) for maternal effects was 2.6 mg/m^3. This LOAEL was based on an increase in lung weights both absolute and relative to brain weights at all exposure levels evaluated. The changes were dose-responsive and differed statistically from controls. The No-Observed-Effect Level (NOEL) for developmental toxicity was 6.3 mg/m^3, the highest exposure level evaluated.

A previous TSCA 8(e) letter pertaining to this same subject was incorrectly submitted due to an address error to the USEPA on February 24, 2004 by the IAOIA. Therefore, this submission is to correct the previous letter and to ensure proper receipt by your office. If you have any questions or other concerns please do not hesitate to phone me at 765-497-6637 or email tserex@glcc.com.

Sincerely yours,

Tessa L. Serex

Tessa L. Serex, Ph.D., D.A.B.T.
Toxicologist
Lead Technical Advisor to IAOIA

Great Lakes Chemical Corp.
One Great Lakes Blvd.
West Lafayette, IN 47996

Appendix A
International Antimony Oxide Industry Association Membership

Campine NV
IZ Kanaal West
Nijverheidsstraat 2
B- 2340 Beerse

Geert Krekel, vice-chair
Tel: +32 14 601 507
geert.krekel@campine.be

Karine Van de Velde, secretary-general
Tel: +32 14 601 578
karine.vandevelde@campine.be

Great Lakes Chemical Corporation

Dave Sanders, chair
One Great Lakes Boulevard
West Lafayette, IN 47906
PO Box 2200
Tel: + 765 497 6319
dsanders@glcc.com

Dieter Drohmann
Sattlerweg 8
51429 Bergisch Gladbach
Germany
Tel: +49 (0) 22 04 95 43 118
ddrohman@glcc.com

Tessa Serex, toxicologist, chair of the technical group
One Great Lakes Blvd
West Lafayette, IN 47906
PO Box 2200
Tel: +765 497 6637
tserex@glcc.com

Laurel Industries, Inc (OxyChem)
Tom Bellanti – Plant Manager
780 South 16th Street
La Porte, TX 77671

Tom Bellanti, treasurer IAOIA
Tel: 281/471-1731 Ext. 111
tom_bellanti@oxy.com

Produits Chimiques de Lucette (Sica)
Z.I. de la Vallée Verte
BP 1
53940 Le Genest Saint Isle
France

Gilles Ozoux
Tel: +33 (0) 2 43 01 23 10
gozoux@pcdlucette.com

Christian Legrand
Tel: +33 (0) 2 43 01 23 10
lucette.quality@wanadoo.fr

Penarroya Oxide Group
60871 Rieux Cedex
Quai de l'Oise
BP 1
France

Giso von Steinrück
Tel: +33 3 44 66 45 40
GVS@penoxgroup.com

Denis Doiseau
Tel: +33 3 44 66 45 41
denis.doiseau@penarroyaoxide.fr

David Hardy
Tel: +44 1925 262153
e-mail ?

Sica SA
Rue Géo Lufbéry
BP 46
02301 Chauny
France

Bruno Dermigny
Tel: +33 3 234 03530
dermigny@sica-chauny.com

Nihon Seiko Co, Ltd
3-2 Shimomiy Abi-cho
Shinjuku-ku
tokyo 162-0822 Japan

Osamu Iwayama
Tel: 03 (3235)0031
iwayama@nihonseiko.co.jp

Yoshiyuki Masumori
Tel: 03 (3235) 0031
masumori@nihonseiko.co.jp

Nissan chemical Industries, Ltd
KOWA Hitotsubashi Building
7-1, 3-Chome, Kanda-Nishiki-Cho
Chiyoda-Ku, Tokyo
Japan 101-0054

Kenji Onuki
Tel: 81-3 3296 8070
onuki@nissanchem.co.jp

Mikuni Smelting & Refining Co, Ltd
50-13, 1-Chome, Juhachijo
Yodogawa-Ku,
Osaka
Japan

Tomoyuki Nakatani
Tel: 06 6399 5331

April 2003

Sumitomo Metal Mining Co, Ltd
11-3, Shimbashi 5-Chome
Minato-Ku
Tokyo 105-8716 Japan

Ken Takahashi
Tel: +81 3 34367865
Ken_Takahashi@ni.smm.co.jp

April 2003